UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WILNELIA CRUZ; SUSAN JACKSON; DEBORAH MCNEILL; ROBERT NOURSE; LUIS TORRES; and MARILYN WALTO,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services;

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK; and

UNITED NETWORK FOR ORGAN SHARING,

Defendants.

Civil Action No.:

COMPLAINT FOR DECLARATORY, INJUNCTIVE AND MANDAMUS RELIEF

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PRELIMINARY STATEMENT

1. Over thirty years ago, Congress passed the National Organ Transplant Act to make clear that donated organs are a national resource that must be equitably distributed on a nationwide basis. The law is clear and unequivocal: allocation of donated organs "[s]hall not be based on the candidate's place of residence or place of listing." 42 C.F.R. §121.8(a). The purpose of the law was unambiguous –to save as many lives as possible. It is equally clear that the law is not currently being followed. In direct contravention of the law, the allocation of deceased donor organs is highly dependent on where a candidate lives. Indeed, one's place of residence or place of listing is the single largest determining factor in a candidate's likelihood of survival. As a result, Congress' effort to save lives has been thwarted and people who could be saved are dying needlessly. This action seeks declaratory, injunctive, and mandamus relief to bring the nation's liver transplant program into compliance with the law.

2. Livers from deceased donors are portable and can be safely preserved for up to 12 hours. Livers from California and Arizona can be and have been successfully transplanted in New York, and livers from Virginia and New York have been successfully transplanted in California, Utah, and Texas. Despite the portability of livers, Plaintiffs who are registered for liver transplants in California, Massachusetts and New York will likely need to wait several years for a transplant, while less-sick candidates 500 or 1,000 miles away will receive transplants in several weeks or months. This disparity results in the death of many waitlist candidates and is the direct result of Defendants' illegal and inequitable liver allocation policy. Defendants fully recognize the illegality and inequity of the current liver allocation policy, as well as how to fix the problem, but to date they have been unable to institute a legal and equitable liver allocation policy.

3. The medical priority of an adult liver transplant candidate is measured using a MELD score (Model for End-Stage Liver Disease). MELD is a numerical scale, ranging from 6 (least ill) to 40 (gravely ill), that measures how urgently a candidate needs a liver transplant within the next three months. A candidate's MELD score is an objective measure of medical need, reflecting the urgency with which the candidate needs a transplant. Without a liver transplant, candidates with a MELD score of 35 or higher have a less than 50% chance of surviving three months while candidates with a MELD score of 20 have an over 90% three month survival rate. Candidates with a life expectancy of less than seven days are given Status 1A priority.

4. The United States Department of Health and Human Services ("HHS") operates the nation's Organ Procurement and Transplantation Network ("OPTN") through a contract with the United Network for Organ Sharing ("UNOS"). The OPTN has 58 Organ Procurement Organizations ("OPO"s) throughout the United States. OPOs are responsible for procuring deceased donor organs for transplantation and each OPO operates in an arbitrarily-determined geographic area called a Donation Service Area ("DSA"). The 58 DSAs are further grouped into 11 regions ("Regions").

5. The size and scope of the DSAs and Regions bear no relationship to population, geography, transportation logistics or medical need. Some DSAs are 1,000 miles wide while others are less than 100 miles wide. Some DSAs have populations as small as 1.4 million, others as large as 20 million. Similarly, one of the 11 Regions contains only two OPOs with a total population of 14 million, while another contains 10 OPOs with a population of 49 million or more.

6. Current OPTN policy allocates livers by MELD score within the DSA or Region before being offered nationally. When a liver becomes available, it must first be made available to candidates within the arbitrary boundaries of the donor's Region with priority status 1A. The liver is then made available to candidates in the donor's DSA and Region with a MELD score of 40, then 39, then 38 and so on until MELD score 15. Only if there are no matching candidates in the DSA or Region with a MELD score of 15 or more is the liver offered nationally.

7. By way of example, consider a patient waitlisted at a hospital in Manhattan with a MELD score of 39, which reflects an extremely high level of medical need. The hospital is a 6.7 mile drive (20 minutes or less) from Englewood Hospital in Englewood, New Jersey. Under current OPTN policy, a liver that becomes available in Englewood, NJ could potentially go to a candidate at University of Pittsburgh Medical Center— which is a 6-hour, nearly 400-mile drive away – even if the Pittsburg candidates have a lower (even much lower) MELD score. Given the arbitrary nature of the DSAs' and Regions' geographic area, the candidate receiving the liver may be both less sick and *geographically further away* from the donated liver than a candidate with higher medical priority.

8. As recognized by the OPTN, there is no legal or medical basis to offer a liver to a candidate with a lower MELD score (and potentially geographically further away). The current system is flawed and results in longer wait times and more waitlist deaths in certain areas of the country. This flaw has been exploited by transplant centers in certain areas of the country to shorten their wait times and encourage those with financial resources to engage in domestic transplant tourism. Unfortunately, for candidates like Plaintiffs current OPTN policy is likely fatally flawed because they do not have the financial means to move to areas of the country with

shorter wait times. Without judicial intervention, Plaintiffs may soon die or become too sick to undergo transplant.

9. The unfairness of the current system is underscored by the most recent OPTN annual report which found "there is wide geographic variability in the degree of sickness, based on median MELD scores, in candidates for deceased donor transplants." Exhibit A at p. 5. The highest reported median MELD score was 39 (*i.e.*, more than 90% likelihood of dying within three months) in Los Angeles, California and the lowest was 20 (*i.e.,* less than 20% likelihood of dying within three months) in Indianapolis, Indiana. Like California, liver transplant candidates in Massachusetts and New York have some of the nation's highest median MELD scores.

10. Despite recognizing the illegality and inequity of the current system, OPTN has failed to institute an appropriate liver distribution policy because of its continued adherence to arbitrary DSA and Region boundaries. In December 2017, the OPTN approved revisions to its liver allocation policy. The revised policy, which has not yet gone into effect, introduces a "150-nautical mile radius proximity circle around the donor hospital" in addition to the existing DSA and Region-based boundaries. This "proximity circle" does not put the new policy in compliance with the law, nor will it meaningfully help reduce disparities in liver allocation because the DSA and Region boundaries are entirely arbitrary. A 150 nautical mile proximity circle is meaningless in a place like California. Without removal of the DSA and Regional boundaries, OPTN's current policy will remain fundamentally arbitrary.

11. Over the last three decades much discussion has been had and many studies have been conducted but the OPTN's institutional paralysis has prevented it from implementing a liver policy that complies with the legislative mandate of nationwide – not "local first" – organ

distribution. It is the Secretary's responsibility to make sure OPTN's policies are equitable and consistent with the law. HHS, OPTN, and UNOS have all failed in their responsibilities.

12. Those that oppose equitable allocation of livers – and who have hijacked OPTN policy for three decades – do so for two reasons: (i) they believe in "local first" distribution and fundamentally disagree with Congress' mandate to distribute organs nationwide; and (ii) they seek to protect the strong financial benefits afforded to transplant programs in areas with short waitlists. These positions are inconsistent with the law and inequitable. Congress made clear, years ago, that organs are a limited resource that should be distributed on a nationwide basis, with first priority to those cases with the greatest medical urgency. Neither a transplant center's financial gain nor "local first" allocation is an appropriate or legally supportable basis for organ distribution.

13. Action by a Court to compel review of OPTN and UNOS organ allocation policy is not unprecedented and appears to be the only way to break thorough the OPTN/UNOS logjam. Only after the filing of a lawsuit challenging OPTN's lung policy on the same grounds did OPTN immediately change its lung allocation policy. The new lung policy did away entirely with DSA and Regional distribution criteria, and moved to a zone-based system. HHS, OTN, and UNOS should do the same immediately with deceased liver distribution policy.

14. Plaintiffs are not looking for any special treatment. They only ask that available livers be allocated by medical priority as required by OPTN policy and legislative mandate. Specifically, Plaintiffs request the Court provide the following relief:

(a) declare that OPTN liver distribution policy based on arbitrarily-drawn DSAs or Regions violates the National Organ Transplant Act (and regulations

promulgated thereunder), since it requires a "nationwide distribution of organs equitably among transplant patients";

(b) order the Secretary and OPTN to implement an appropriate zone-based liver distribution policy (e.g., 1,000 mile zone) within 6 months; and

(c) enjoin the Secretary and OPTN from implementing a new liver allocation policy that is inconsistent with the requirement that livers be equitably allocated among transplant patients.

PARTIES, VENUE AND JURISDICTION

15. Wilnelia Cruz is a resident of New York, New York, who is currently waitlisted for a liver transplant at a New York area transplant center. She has two children. She suffers from a liver illness she contracted in a blood transfusion when she was a baby. She was added to the liver transplant waiting list in January 2017. Ms. Cruz does not have the financial means to travel to a transplant center with shorter wait times outside of the New York area.

16. Susan Jackson is a resident of southern California, who is currently waitlisted for a liver transplant at a California transplant center. Ms. Jackson does not have the financial means to travel to a transplant center with shorter wait times outside of California.

17. Deborah McNeill is a resident of Massachusetts, who is currently waitlisted for a liver transplant at a Massachusetts transplant center. Ms. McNeill does not have the financial means to travel to a transplant center with shorter wait times outside of Massachusetts.

18. Robert Nourse is a resident of northern California, who is currently waitlisted for a liver transplant at a northern California transplant center. Mr. Nourse does not have the financial means to travel to a transplant center with shorter wait times outside of California.

19. Luis Torres is a resident of Bronx, New York who is currently waitlisted for a liver transplant at a New York area transplant center. He is married and has three children. Louis suffers from liver cirrhosis with cancer that can be cured with a timely liver transplant but is likely to spread if he is not transplanted in the near term. He was added to the liver transplant list in March, 2017. Louis is currently unemployed due to his medical condition. Louis receives health benefits through Medicaid, which prevents him from traveling outside New York for a transplant. He also does not have the financial means to travel and relocate for a liver transplant.

20. Marilyn Walto is a resident of Massachusetts, who is currently waitlisted for a liver transplant at a Massachusetts transplant center. Ms. Walto does not have the financial means to travel to a transplant center with shorter wait times outside of Massachusetts.

21. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services, located at 200 Independence Ave., S.W., Washington, DC 20201. Defendant Azar is sued in his official capacity.

22. The Organ Procurement and Transplantation Network was established by the National Organ Transplant Act ("NOTA") passed by the U.S. Congress in 1984. By Congressional mandate, the Secretary of HHS is responsible for contracting for the establishment and operation of an OPTN consistent with the requirements of NOTA.

23. Defendant United Network for Organ Sharing is a Virginia non-stock, not-for-profit corporation. UNOS operates the OPTN through a contract with the Health Resources and Services Administration ("HRSA") of HHS, and accordingly is responsible for the fair and equitable distribution of all donated organs, including livers. UNOS maintains a computerized database to identify potential transplant recipients and to systematically match donated organs with such recipients. All OPOs and transplant facilities in the United States are required to be

members of OPTN. UNOS's Board of Directors is currently made up of 42 voting members elected from UNOS's membership and the general public.

24. This action arises under NOTA, 42 U.S.C. § 274, *et seq.*, the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, Federal Regulations 42 C.F.R. part 121, *et seq.* and the United States Constitution.

25. Jurisdiction is present under 28 U.S.C. § 1331 because the "district courts have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Jurisdiction is also present under the APA, which authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). The APA also authorizes a court to "set aside agency action, findings, and conclusions of law found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law," and provides a right to judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 706(2) and 704.

26. Jurisdiction is present against OPTN and UNOS pursuant to CPLR 302(a) and FRCP 4(k)(1)(A). OPTN and UNOS transact business within New York by collecting registration fees from residents and transplant centers in New York and by procuring organs and administering the organ matching and distribution system within New York.

27. This Court has authority to issue a declaratory judgment and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202.

28. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(e)(1) because at least one plaintiff currently resides in this district, there is no real property involved in the action,

and at least one defendant is an officer of the United States or agencies thereof and acting in his official capacity.

BACKGROUND

A. The National Organ Transplant Act

29. On December 23, 1954, Dr. Joseph Murray performed the first successful organ transplant when he transplanted a kidney between identical twins at Brigham and Women's Hospital in Boston. Over a decade later, Dr. Thomas Starzl at the University of Colorado performed the first successful liver transplant.

30. In the 1970s and 1980s several medical breakthroughs in the fields of tissue typing and immunosuppressant drugs led to an increased number of organ transplants and improved survival rates for recipients. The most notable development in this area was the discovery of the immunosuppressant cyclosporine, which transformed transplants from experimental or research surgery into everyday life-saving treatment. Additionally, development of preservation solutions during this time allowed organs to be transported across the country while maintaining their viability. By the 1980s, U.S. doctors performed over 10,000 organ transplants each year, primarily kidney and liver transplants.

31. In 1968, the first organ procurement organization, the New England Organ Bank, was established in Boston. Around that time, the National Conference of Commissioners on Uniform State Laws drafted the Uniform Anatomical Gift Act and established the Uniform Donor Card as a legal gifting document in all 50 states.

32. Over the next two decades the number of U.S. organ procurement organizations grew substantially. Most of these organizations were centered in research hospitals and were formed to provide local hospitals with organs necessary for their transplantation programs.

Organs that could not be used at local hospitals often went to waste because no system existed to match candidates outside the local area with available organs, and because deceased organ preservation times were substantially shorter than they are now.

33. In 1977, the Southeastern Organ Procurement Foundation (SEOPF), an association of donation and transplant professionals, established a computerized database to help member institutions list candidates and find matches for organs they could not use locally. That database was called the United Network for Organ Sharing, which eventually became UNOS.

34. The National Organ Transplant Act was signed into law on October 19, 1984. NOTA authorized the Secretary of HHS to make grants for organ procurement organizations, created the OPTN and created the Scientific Registry of Transplant Recipients ("SRTR"). NOTA also made it a crime to sell organs.

35. NOTA, as originally passed in 1984, envisioned a "local first" distribution of organs. Consistent with how organ transplantation developed, organs would first be made available to local matching candidates and thereafter be offered for distribution more broadly. The 1984 version of NOTA provided that the OPTN shall ''assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations.'' (emphasis added.)

36. In 1988, Congress passed the Organ Transplant Amendments of 1988, which reversed course by doing away with "local first" organ distribution and removing NOTA's reference to locally prioritized organ distribution. Following the 1988 amendment, NOTA provided that the OPTN shall: ''assist organ procurement organizations in the distribution of organs ~~which cannot be placed within the service areas of the organizations~~.'' The Senate Report relating to the 1988 amendment explained that the referenced language was struck "to

remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients.'' S. Rep. No. 100–310 at 14–15 (1988).

37. Two years later, Congress once again amended NOTA to further confirm that organs were deemed a national resource that should be distributed as equitably as possible on a nationwide basis and without local prioritization. S. Rep. No. 101-530 (1990) (amending language to "emphasize that the OPTN has a nationwide service area.")

38. Following the 1990 amendment, NOTA provided that the OPTN shall "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients." (emphasis added) The relevant language of NOTA has not changed since 1990 and is codified as 42 USC 273 *et. seq.*

The Organ Procurement and Transplantation Network shall:	
1984 NOTA	assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations
1988 NOTA	assist organ procurement organizations in the distribution of organs ~~which cannot be placed within the service areas of the organizations~~
Current (1990) NOTA	assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.

B. The Final Rule

39. NOTA vests with HHS the responsibility for managing the United States' organ donation and transplant network. In furtherance of NOTA, on April 2, 1998, HHS published in the Federal Register a Final Rule governing operation of the OPTN. 63 Fed. Reg. 16296-338 (April 2, 1998). The Final Rule generally addresses HHS's oversight of the OPTN and OPTN's role in setting organ distribution policy. A copy of the Final Rule is attached as Exhibit B.

(a) Abolishment of the "Local First" Practice

40. One of the drivers of the Final Rule was HHS' concern that OPTN organ distribution policy was inconsistent with NOTA. Specifically, HHS stated that:

> While present OPTN policies give weight to medical need, the ''local first'' practice thwarts organ allocation over a broad area and thus prevents medical need from being the dominant factor in allocation decisions.
>
> **Under the provisions of this rule, it is intended that the area where a person lives or the transplant center where he or she is listed will not be primary factors in how quickly he or she receives a transplant. Instead, organs will be allocated according to objective standards of medical status and need.** In this way, suitable organs will reach patients with the greatest medical need, both when they are procured locally and when they are procured outside the listed patients' areas. This objective reflects the views of many commenters on the proposed regulations, as well as the finding of the American Medical Association in its *Code of Medical Ethics*: ''**Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.**''

63 Fed. Reg. 16297 (April 2, 1998) (emphasis added).

41. The Final Rule required the OPTN to develop proposals for new organ distribution policies within one year of the effective date of the Final Rule. For livers, the Final Rule provided that because "policy development work has been underway for several years, the OPTN is required to develop a new proposed allocation policy within 60 days of the effective date." Id.

42. HHS and Congress postponed the effective date of the Final Rule numerous times. On October 20, 1999, HHS published in the Federal Register certain amendments or improvements to the Final Rule ("Amended Final Rule") to reflect comments received by HHS, including from the National Academy of Science's Institute of Medicine ("IOM"). 64 Fed. Reg. 56650-61 (October 20, 1999).

43. The Amended Final Rule reiterated and reemphasized the need for OPTN policy to reflect broad sharing of organs based on medical urgency and not arbitrary geographic boundaries. The Amended Final Rule provides:

> As underscored by the IOM recommendations, it is the Department's goal to achieve sharing of organs broad enough to achieve medically effective results for patients, especially by providing organs for patients with greatest medical urgency who are appropriate candidates for transplantation. When using the terms ''greatest medical urgency,'' or ''most medically urgent,'' the Department is referring to transplanting those patients whose medical condition, in the judgment of their physicians, makes them suitable candidates for transplantation. **The final rule directs the OPTN to overcome as much as possible arbitrary geographic barriers to allocation that restrict the allocation of organs to patients with greatest medical urgency who are appropriate candidates for transplantation and that are not based on medical criteria. Broader sharing was an essential element of the IOM's findings.**

64 Fed. Reg. 56651 (October 20, 1999) (emphasis added).

44. The Amended Final Rule also strengthened HHS's authority over OPTN and gave HHS the power to determine whether policies proposed by OPTN were consistent with NOTA. The Amended Final Rule became effective on March 16, 2000.

(b) Regulation of the OPTN

45. The Final Rule (as amended) is codified at 42 CFR § 121. These regulations provide the regulatory framework within which the OPTN and SRTR operate.

46. OPTN Board of Directors. The Final Rule provides that the OPTN shall be a private, not for profit entity with a Board of Directors. 42 CFR § 121.3. The Final Rule provides that the OPTN Board of Directors should consist of: (i) transplant physicians and surgeons (approx. 50%); (ii) transplant candidates, transplant recipients, organ donors and family members (at least 25%); and (iii) representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public. 42 CFR § 121.3(a)(1). The Final Rule does not include

any requirement that the Board of Directors come from different areas of the country or that each Region be represented on the OPTN Board of Directors.

47. OPTN Policy Process. The OPTN Board of Directors is responsible for developing policies, among other things, "for the equitable allocation of cadaveric organs in accordance with §121.8." As it develops allocation policies, the OPTN must provide notice to OPTN membership and the Secretary regarding its proposals. Those proposed policies do not become enforceable until approved by the Secretary. The Secretary is tasked with determining whether the proposed policies are consistent with NOTA and the Final Rule. If the Secretary concludes that a proposed policy is inconsistent with NOTA or the Final Rule, the Secretary may take such other action as the Secretary determines appropriate, after additional consultation with the Advisory Committee on Organ Transplantation. 42 CFR 121.4.

48. OPTN Policy Development. The Final Rule provides that OPTN's Board of Directors shall establish policies "for the equitable allocation of cadaveric organs among potential recipients" and that such policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each

transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

42 CFR. §121.8(a) (emphasis added).

49. Performance Goals. In addition to these specific allocation policies, the Final Rule also established "performance goals to be achieved by the OPTN." 63 Fed. Reg. 16296 (April 2, 1998). The performance goals are intended to provide a benchmark "against which the OPTN can reform current allocation policies." 63 Fed. Reg. 16324 (April 2, 1998). One of the performance goals of OPTN policy is to distribute organs over as broad a geographic area as feasible in order of decreasing medical urgency. 42 CFR. §121.8(b)(3).

50. As explained in the Final Rule, the purpose of this performance goal is as follows:

> Equitable Allocation—The OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment. This increases the likelihood of patients obtaining matching organs, **and gives all patients equal chances to obtain organs compared to other patients of equal medical status, wherever they live or list.**
>
> By requiring common criteria for listing eligibility and medical status, and by **requiring that organs be directed so as to equalize waiting times**, especially for those with greatest medical need, this rule is designed to provide patients awaiting transplants with equal access to organs and to provide organs to sickest patients first, consistent with sound medical judgment.

63 Fed. Reg. 16296-97 (April 2, 1998) (emphasis added).

(c) The Scientific Registry of Transplant Recipients (SRTR)

51. In addition to the establishment of the OPTN, NOTA also provided for the establishment of "a scientific registry of the recipients of organ transplants" for purposes of providing HHS with "such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation." 42 U.S.C. 274(a).

52. The Final Rule provides that OPTN allocation policies be based on "sound medical judgment" and "reviewed periodically and revised as appropriate." 42 CFR. §121.8(a). It is the responsibility of the SRTR to provide the OPTN and HHS with analytic support and evidence necessary to support the development and evaluation of, among other things, organ allocation and distribution policy.

53. The SRTR is tasked with publishing an annual data report with data on organ donation and transplantation, including analyses describing recent activities and trends over time. The SRTR is also tasked with assisting HHS with preparing a Biennial Report to Congress on the Scientific and Clinical Status of Organ Transplantation as required by NOTA. 42 U.S.C. 274(d).

C. UNOS

54. UNOS is the government contractor that operates the OPTN through a contract with HRSA. UNOS is responsible for administering the OPTN and furnishing all the necessary services, personnel, equipment, and facilities to support the OPTN functions. UNOS maintains a computerized database to identify potential transplant recipients and to provide for the systematic matching of donated organs with such recipients.

55. UNOS was awarded its initial contract in 1986 to develop the requirements for the operation of the OPTN and has served the OPTN ever since. UNOS is funded largely by OPTN/UNOS registration fees and HHS contract payments. The current OPTN registration fee is $834, paid by transplant hospitals to register a transplant candidate on the OPTN waiting list. UNOS charges a fee of $145 per candidate registration.

56. As of September 30, 2017, UNOS had net assets of $47.5 million and FY 2017 revenues of over $77 million. UNOS employs 350 people. UNOS is governed by a Board of Directors of 42 members. Brian Shepard serves as its chief executive officer.

D. Achieving Equitable Nationwide Distribution of Organs

57. Equitable nationwide distribution must balance medical urgency with the viability of the donated organ, *i.e.*, the length of time a deceased organ can survive before it deteriorates.

58. Medical urgency is usually determined by a scoring system that ranks candidates based on their medical condition and likelihood of survival without a transplant. For adult liver candidates the MELD scoring system is used. For candidates 11 and younger the Pediatric End-stage Liver Disease (PELD) scoring system is used. Lungs use a Lung Allocation Score (LAS) and hearts are ranked on a Status 1 through 6.

59. Hearts and lungs have a preservation time that is half as long as livers (approx. 6 hours) and will accordingly have a more limited geographic reach. Current OPTN policy uses four different geographical areas for organ distribution: Zones, DSA, Region and Nation.

(a) Zones

60. OPTN Policy provides for a zone-based allocation system for certain organs. A zone, in OPTN parlance, is a geographic area encompassed within a circle drawn around a donor hospital at the circle's center. Larger zones expand concentrically, maintaining the donor hospital at the center. For example, in the context of lung allocation, current OPTN policy has six zones (A through F). Zone A includes all transplant hospitals within 250 nautical miles of the donor hospital. Zone B includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of Zone A. Zones C through F extend further away from the donor hospital in 1,000, 1,500, 2,500, and >2,500 mile increments as shown below.

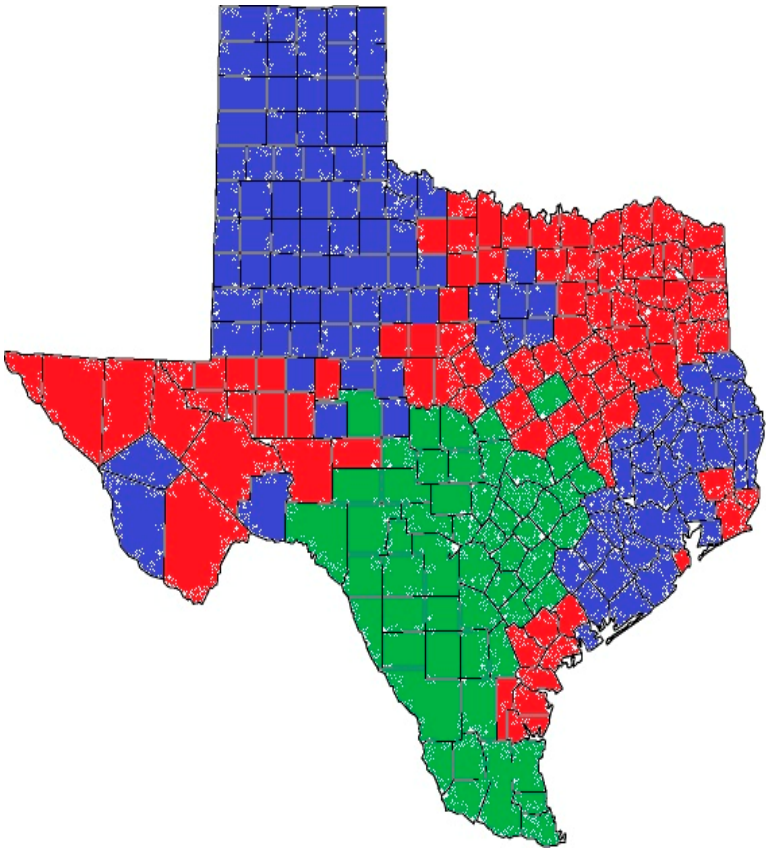
61. OPTN uses zone-based allocation for lungs and, in part, for hearts. Zone-based allocation, as compared to DSA or Region allocation, is recognized by the OPTN Executive Committee to "to minimize the effect of geography on a candidate's access to donors by providing urgent candidates access to a broader range of donors across DSA, and sometimes even across regional, borders."

(b) OPO's Donation Service Area

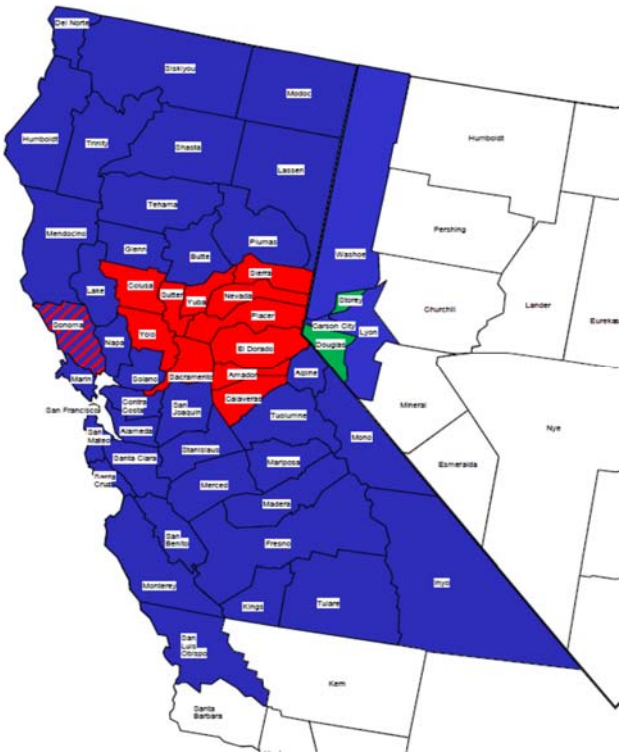
62. There are currently 58 OPOs, or organ procurement organizations, in the United States. Each OPO is designated to a specific geographic area, which is referred to as a donation service area or DSA. OPOs have agreements with each of the hospitals in their respective DSAs to coordinate organ recovery, donation, and transplantation.

63. The OPO DSAs are arbitrary in size, shape, and population. They also vary greatly in number of deaths in the population at large, with an especially high variance for deaths that are most likely to lead to organ donation (i.e., strokes, vehicle accidents, and preventable homicides). Data prepared by the SRTR shows that DSA populations range from under 1.5 million to over 20 million, and that the 16 largest DSAs contain over 50% of the U.S. population. Similarly, the geographic size of DSAs vary greatly from 3,557 sq. miles to 808,360 sq. miles. The seven geographically largest OPO's DSAs cover approximately 50% of the area of the U.S.

64. Many of the OPO DSAs are oddly shaped. Consider the three OPOs serving Texas in the accompanying graphic: (i) LifeGift Organ Donation Center (OPO Code: TXGC), shown in blue; (ii) Southwest Transplant Alliance (OPO Code: TXSB), shown in red; and (iii) Texas Organ Sharing Alliance (OPO Code: TXSA), shown in green. Each of the three OPO's DSAs stretch across non-contiguous areas, and their geographic coverage is arbitrary, bearing no relationship to area, population or travel time. LifeGift Organ Donation Center has coverage in three different corners of the state over 700 miles apart, while the Fort Worth – Dallas metropolitan area is split between two different OPOs.



65. Another example is the west coast DSA of OPO Donor Network West (OPO Code: CADN), which serves much of northern California except for various carve-outs around Sacramento, Sonoma County and western Nevada, which peculiarly are covered by different OPOs. The areas shown below in blue are Donor Network West's geographic area. The areas in red are covered by Sierra Donor Services (OPO Code: CAGS) and the areas in green by Nevada Donor Network (OPO Code: NVLV).



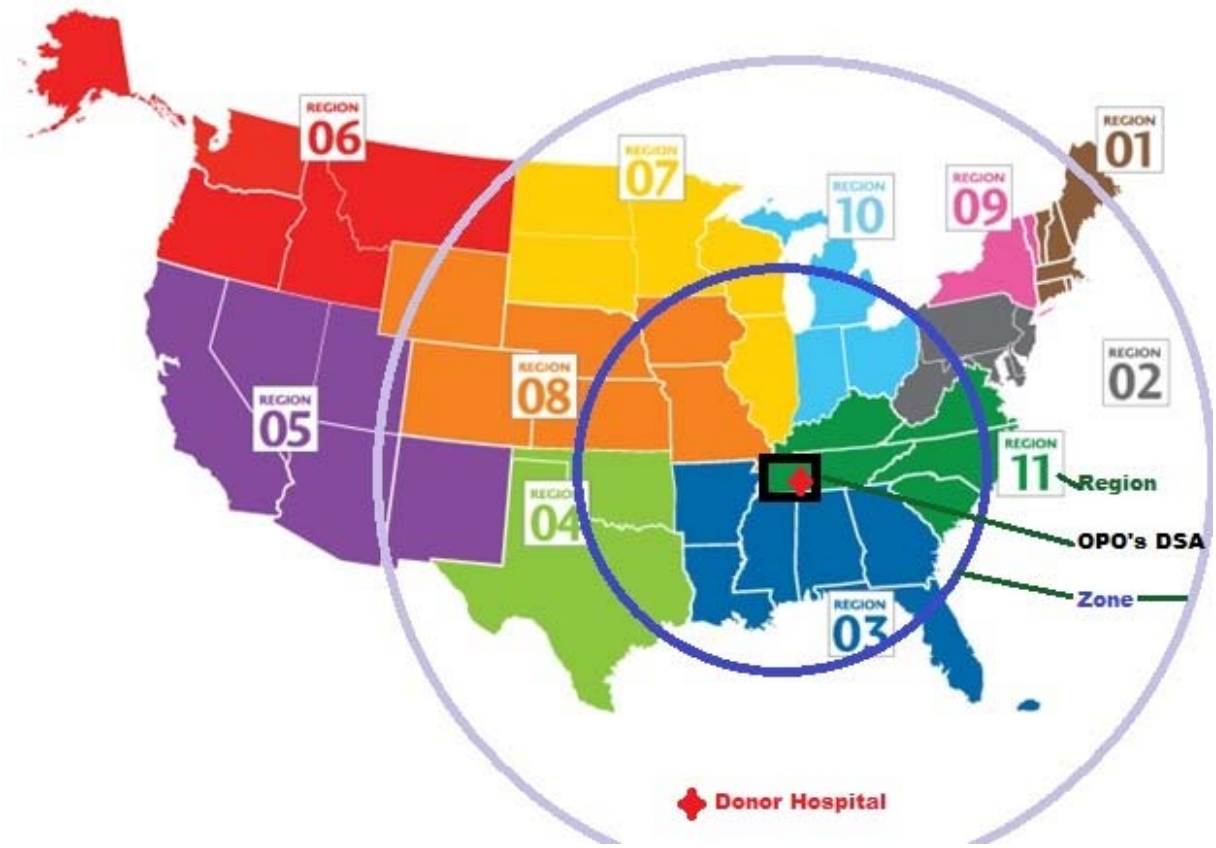
66. The size and shape of a DSA is a vestige of historical grouping of organ procurement organizations and has no bearing on distance, travel time or viability of an organ. Using and OPO's DSAs for organ distribution is entirely arbitrary and without any rational basis.

(c) Regions

67. OPTN bylaws provide for its OPO members to be divided into 11 regions for the "administration of organ allocation and appropriate geographic representation within the OPTN policy structure." Like the OPOs DSAs, the Regions are arbitrary in size, number of deaths, and population, and are merely a function of administrative convenience.

68. Regions have populations ranging from 14.4 million to over 54.6 million. Region 1 has two OPOs and Region 3 has ten OPOs. Region 9 has a land area of 51,346 sq. miles (smaller than Florida) while Region 6 has a land area almost 20 times as large. A map of the 11

OPTN Regions with an overlay of the relevant DSA, and a 500 nm zone and 1,000 nm zone is set forth below.



69. Although the Final Rule has no such requirement, OPTN's bylaws require the OPTN Board of Directors to "include regional councillors who are representatives chosen by the voting members and member electors of each of the 11 geographic regions in the United States." OPTN Bylaws § 2.1.B. (effective March 1, 2018). This requirement is, in part, responsible for OPTN's inability to make meaningful progress on equitable distribution of organs. For example, although Region 5 has seven times more patients on the liver waitlist than Region 6, Region 5 gets the same representation on the OPTN Board of Directors. While meaningful representation from all constituents is important, it should not be used to create institutional paralysis that results in illegal and inequitable distribution policies.

(d) Nation

70. Some organs have as part of their distribution priority nationwide sharing. For example, intestines are shared nationwide if no match is found in the OPO's DSA or Region. OPTN Policy Table 7.1. Similarly, livers are shared on a nationwide basis if there are no candidate matches in the OPO's DSA or Region with a MELD score of at least 15. OPTN Policy Table 9.6.

E. Current OPTN/UNOS Liver Allocation Policy

71. OPTN Policy 9 sets forth the rules for distribution and allocation of livers. Policy 9.6.E. (Allocation of Livers from Deceased Donors at Least 18 Years Old) provides that "[l]ivers from deceased donors at least 18 years old are allocated to candidates according to *Table 9-6* below." Table 9.6 (Allocation of Livers from Deceased Donors at Least 18 Years Old) sets forth 52 classifications of distribution and allocation priority, the first 22 of which are listed below.

Table 9-6: Allocation of Livers from Deceased Donors at Least 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's region	Adult or pediatric status 1A
2	OPO's region	Pediatric status 1B
3	OPO's DSA	MELD/PELD of 40
4	OPO's region	MELD/PELD of 40
5	OPO's DSA	MELD/PELD of 39
6	OPO's region	MELD/PELD of 39
7	OPO's DSA	MELD/PELD of 38
8	OPO's region	MELD/PELD of 38
9	OPO's DSA	MELD/PELD of 37
10	OPO's region	MELD/PELD of 37
11	OPO's DSA	MELD/PELD of 36
12	OPO's region	MELD/PELD of 36
13	OPO's DSA	MELD/PELD of 35
14	OPO's region	MELD/PELD of 35
15	OPO's DSA	MELD/PELD of at least 15
16	OPO's region	MELD/PELD of at least 15
17	Nation	Adult or Pediatric status 1A
18	Nation	Pediatric status 1B
19	Nation	MELD/PELD of at least 15
20	OPO's DSA	MELD/PELD less than 15
21	OPO's region	MELD/PELD less than 15
22	Nation	MELD/PELD less than 15

72. As explained in UNOS literature, the liver allocation process works as follows:

First, transplant candidates that are not compatible with the donor based on a number of characteristics (blood type, height, weight, etc.) are screened from the match run that determines the order a liver is offered. The remaining candidates on this match run are prioritized based on the following factors:

- the donor's age
- their medical urgency
- their geographical proximity to the donor (local–defined by the Organ Procurement Organization's service area; regional –UNOS has 11 allocation regions in the U.S.; national-all remaining candidates in the nation)

Livers from adult donors are allocated first to the most urgent candidates located in the same region as the donor; Status 1A candidates, followed by Status 1B candidates. The allocation sequence provides broader access to those most in

need of a liver (those with scores higher than 35) and those who would receive the most benefit (those with scores higher than 15). Therefore, after regional Status 1A and 1B candidates, liver offers are then made to:

- candidates with MELD/PELD scores 35 and higher within the donor's region, with offers first made locally, then regionally (i.e., local 40) regional 40, local 39, regional 39, etc.)
- local candidates with scores greater than 15
- regional candidates with scores greater than 15
- national candidates in Status 1A or 1B
- national candidates with scores greater than 15
- candidates with scores less than 15 locally, regionally, then nationally.

Exhibit C – UNOS Publication, *Questions and Answers for Transplant Candidates about the Liver Allocation System* at pp. 3-4.

73. Under the current system, if a liver is accepted for a candidate listed with a MELD score within the local DSA, it is not offered to a candidate in the broader reach of the organ even if that non-local DSA candidate has a greater medical need, i.e., a higher MELD. Moreover, because of the arbitrary boundaries of DSAs, an available liver may not even be offered to the candidate closest to the donor hospital even if that candidate has a higher MELD. Instead of following such a patently illogical distribution priority rule, organs should be made available to a candidate based on a logistically reasonable radius to the transplant hospital. Although livers have a preservation of time that is 200% of hearts and lungs – up to 12 hours or longer – livers are still distributed based on arbitrary local boundaries, while other organs, like lungs, have transitioned to a non-arbitrary zone-based prioritization.

74. OPTN claims that "[h]earts and lungs have less time to be transplanted, so we use a radius from the donor hospital instead of regions when allocating those organs." Exhibit D.

This is nonsensical. As shown in the figure following paragraph 68, there is no relationship between Region and distance. The radius of a 500 nm zone does not necessarily encompass the entirety of a Region, and there are nearly always places in a 500 nm zone that extend outside a given Region. Simply put, OPTN Policy 9 is arbitrary and violates the legislatively mandated requirement that organ allocation be "based on sound medical judgment" and "not be based on the candidate's place of residence or place of listing." 42 C.F.R. §121.8(a).

F. OPTN/UNOS's Revised but Not Implemented Liver Policy

75. In 2017, the OPTN Board of Directors approved two changes to the liver allocation policy: (i) a new liver distribution policy; and (ii) a National Liver Review Board.

76. The new liver distribution policy, approved by the OPTN Board in December 2017, introduces the following changes:

(a) A 150-nautical mile radius proximity circle around the donor hospital will be used as part of the distribution priority.

(b) Candidates who have a calculated MELD score of 32 or higher will receive priority.

(c) Transplant priority (in the form of 3 MELD points) will be granted to candidates who are either within the same DSA or within 150 nautical miles of the donor hospital.

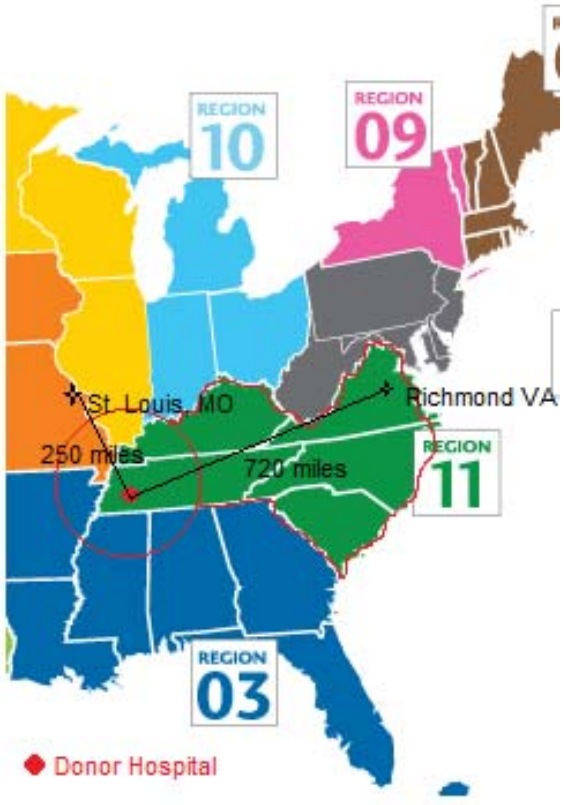
77. The new liver policy would replace the current prioritization table as follows:

Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	Region or Circle	Any of the following: •At least 18 years old at time of registration and calculated MELD of at least 32 including proximity points •At least 18 years old at time of registration and has an approved HAT exception •Less than 18 years old at time of registration and allocation MELD or PELD of at least 32 including proximity points
4	DSA	MELD or PELD of at least 15
5	Region or Circle	MELD or PELD of at least 15

78. Crucially, the new policy's "proximity circle" does not put the new policy in compliance with the law nor does it meaningfully help reduce disparity in liver allocation. The DSA and Regional boundaries remain arbitrary. Adding a 150 nautical mile proximity circle without removing the arbitrary boundaries has no medical or legal basis. Moreover, the 150 nautical mile circle is less than that used for lungs although livers have a preservation time that is twice as long as lungs. The 150 nautical miles circle can have some effect on the availability of donors for a given candidate or virtually no effect at all, based on the size and shape of the Region in which the candidate is located and the candidate's location within the Region.

79. For example, as shown below, a liver donated at Methodist Hospital in Memphis, Tennessee would, under the new rules, still travel 720 miles to a less ill person in Richmond, Virginia instead of traveling only 250 miles to a gravely ill candidate in St. Louis, Missouri. Moreover, as shown, the 150 nautical mile proximity circle mostly includes areas that are already within the region. In some areas of the country the change is meaningless. For example, the 150

nautical mile proximity circle has virtually no impact in California or Region 6 because the proximity circle is entirely encompassed within the Region.



80. The revised liver distribution policy is currently expected to be implemented in December 2018. The revised liver policy is, however, just as illegal and inequitable as the current liver policy because, as the OPTN recognizes, "like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates." Exhibit E at p. 3. Regions are as arbitrary as DSAs and the allocation of livers by Region has no basis under NOTA or the Final Rule.

81. In June 2017, the OPTN Board also approved a new National Liver Review Board (NLRB) "to provide fair, equitable, and prompt peer review of exception candidates." Exhibit F at p. 3. The NLRB is intended to change the way MELD exception points are determined and assigned. The NLRB is expected to assign exception points to candidates at a fixed value just

below the median MELD at transplant for adult recipients within the DSA. While there are valid aspects to the NLRB, the use of DSA-influenced MELD score, as manifested by setting exception points to just below the median MELD in the DSA, is arbitrary and inconsistent with the law, and it infects what is supposed to be an objective measure of medical need with arbitrary geographic factors.

82. The NLRB is currently expected to be implemented in October 2018.

G. OPTN/UNOS Recognizes that its Current and Revised Liver Allocation Policies Are Inequitable and Illegal

83. OPTN and UNOS has repeatedly recognized that its current and revised liver policies are inequitable and in violation of the Final Rule. Indeed, in "November 2012, the OPTN/UNOS Board of Directors agreed that geographic disparities in candidate access to liver transplants are unacceptably high." Exhibit G at p. ii.

84. Below are some highlights from actual HHS, OPTN and UNOS statements on how the current and revised liver allocation policies violate the Final Rule.

> Currently there is significant variation in a liver transplant candidate's chances of receiving a lifesaving organ offer depending on where they live and the location of the transplant hospital where they are listed.

Exhibit H – OPTN/UNOS Public Comment Proposal at p. 1 (August 15, 2016).

> However, these efforts will not change the fact that the current regional boundaries often physically separate areas with a greater number of candidates from areas with comparably more eligible donors. The result is that in some areas of the United States, candidates must reach a much higher MELD or PELD score in order to get a transplant. Among the current OPTN/UNOS regions in 2015, the difference in median MELD at transplant is as great as 12 points (35 vs 23), the equivalent of a 60 percentage point difference in the estimated risk of 3-month mortality without a liver transplant.

Exhibit H – OPTN/UNOS Public Comment Proposal at p. 1 (August 15, 2016).

> Despite the success of broader sharing in allocating livers to candidates with the greatest medical urgency within a region, the geographic disparity in severity of

> disease at transplant persists (Figure 2). This is because organ distribution is still based upon the current regional borders.

Exhibit H – OPTN/UNOS Public Comment Proposal at p. 3 (August 15, 2016).

> In 2013, 1,523 candidates (an average of eight per day) died while waiting for a liver transplant. Another 1,552 were removed from the waiting list because they were considered too ill to transplant. Candidates in some parts of the country must wait until they are very sick before they receive a liver transplant, while those in other parts of the country may receive transplants when they are much less ill.

Exhibit G – Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation: A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee at p. i (2014).

> Regional and donation service area (DSA) boundaries determine current liver distribution. This leads to a situation where a medically urgent candidate, who may be in close proximity of the donor, but outside of the defined region, has limited access to the donor organ.

Exhibit I – OPTN/UNOS Policy Notice: Enhancing Liver Distribution (December 21, 2017) at p. 1.

> While the regions provide an effective mechanism for participation in the OPTN, neither the regional boundaries nor the DSA boundaries were designed to optimally distribute organs.

Exhibit I – OPTN/UNOS Policy Notice: Enhancing Liver Distribution (December 21, 2017) at p. 2.

> Mr. Shepard [UNOS's CEO] referred to a slide showing that a candidate's geographical location has a significant influence on whether a candidate will get a liver within 90 days. The variability in probability can vary from 20 percent to 30 percent in some Donation Service Areas to 80 percent in others, a fact that the UNOS board has deemed intolerable.

Exhibit J – Advisory Committee on Organ Transplantation p. 6 (November 17, 2015).

> [C]urrent regional boundaries often physically separate urgent candidates from donors in close proximity. The result is that in some areas of the United States, candidates must reach a higher MELD or PELD score in order to get a transplant.

https://optn.transplant.hrsa.gov/governance/public-comment/enhancing-liver-distribution/

> [T]here is wide geographic variability in the degree of sickness, based on median MELD scores, in candidates for deceased donor transplants []. The highest

> reported median MELD score was 39, in Los Angeles, California (CAOP), and the lowest 20 in Indianapolis, Indiana (INOP).

Exhibit A – OPTN/SRTR's 2016 Annual Data Report: Liver (January 2, 2018) at p. 5.

> Despite previous liver policy changes, which were aimed primarily at reducing waiting list mortality, the aggregate measure of disparity did not change appreciably over the past 7 years. Even more so than for kidney, disparities in liver access by DSA far exceeded disparities associated with other factors. Transplant access by DSA was generally consistent as measured by ATS vs. MMAT.

UNOS Research Presentation at 2018 American Transplant Congress.[1]

> Nonetheless, the OPTN previously recognized and again confirms that DSAs are not a good proxy for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs as drawn today are not rationally determined in a manner that can be consistently applied equally for all candidates.

Exhibit E – June 25, 2018 OPTN Letter at p. 2.

> However, like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates.

Exhibit E – June 25, 2018 OPTN Letter at p. 3.

> However, because of the variation in DSAs across the country, the use of DSAs are not optimal units of geography to represent proximity between a donor and candidates to determine the award of proximity points to specific candidates.

Exhibit E – June 25, 2018 OPTN Letter at p. 3.

85. The U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation ("ACOT") was established to assist the HHS Secretary with regard to organ donation and allocation issues. In 2010, ACOT reviewed the issue of disparity in liver allocation noting that:

> The number of patients on the waiting list at the end of the year was about 4,500 individuals who needed livers with a MELD over 20 being added per year. **Livers**

[1] Stewart D., Robinson A., Harper A., Klassen D. Measuring and Monitoring Equity in Access to Deceased Donor Liver Transplants *Am J Transplant*. 2017;17 (suppl 3).

> **are going to less-sick patients** and more effective allocation systems are needed. In addition, **arbitrary geographic boundaries prevent access to transplantation**. **There are enough livers to transplant everyone with a MELD over 21, but the organs are not being distributed appropriately**.

Following discussion, ACOT made the following unanimous recommendation to the Secretary of HHS:

> ACOT believes that the current status does not comply with the intent of the OPTN Final Rule. The ACOT acknowledges that the OPTN has made efforts to revise the liver allocation policy to achieve broader geographic distribution of deceased donor livers with the goal of reducing mortality on the waitlist and equalizing access to transplantation for individuals most urgently in need of transplantation. The OPTN must seek to minimize inequities due to arbitrary geographic barriers to distribution.
>
> Recommendation
>
> The ACOT recommends that the Secretary take steps to ensure that the OPTN develop evidence-based distribution policies that are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions, and state boundaries.

Exhibit K – Advisory Committee on Organ Transplantation, Hyatt Regency Bethesda, Maryland, August 19, 2010 at p. 35.

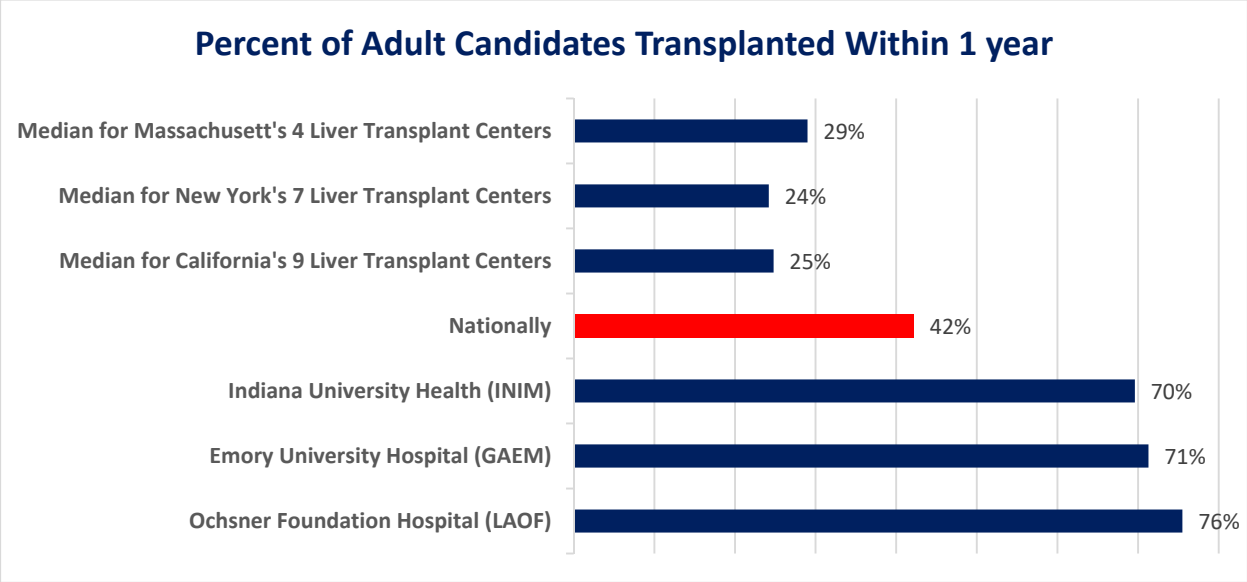
86. For three decades, OPTN has failed to implement a legal and equitable liver distribution and allocation policy because of its continued adherence to OPO and DSA boundaries. There is no legal or medical basis for these arbitrary boundaries to have any role in liver allocation. As recognized by the OPTN, "DSAs might not be the best proxy for geography, as DSAs have disparate sizes, shapes, and populations. DSAs as drawn today do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates." Exhibit L – OPTN/UNOS Mini Brief at p. 2. While some geographic limitation may be necessary to account for the preservation time of organ, any geographic limitation should be zone-based and designed in an equitable manner.

H. Inequality in Liver Distribution Results in Longer Wait Times and Increased Number of Deaths

87. Inequality in liver allocation has grave consequences for thousands of Americans by increasing the wait time for liver transplants and increasing median MELD at transplant.

88. Wait Times. The SRTR recognizes that wait time, or how fast after listing a candidate gets a liver transplant, is the factor that has the "greatest impact for liver candidates." Exhibit M – SRTR website. The SRTR publishes data for each transplant center focusing on numerous metrics including wait times. Consistent with SRTR's annual report, SRTR transplant center data shows great disparity in wait times and transplant rate depending on the area of the country where a candidate is listed.

89. By way of example, and as set forth in the chart below, a transplant candidate in California or New York has an approximately 25% chance of getting a liver transplant within a year of listing while a candidate in Indiana, Georgia or Louisiana has a 70-76% chance of being transplanted in that same time period.[2]

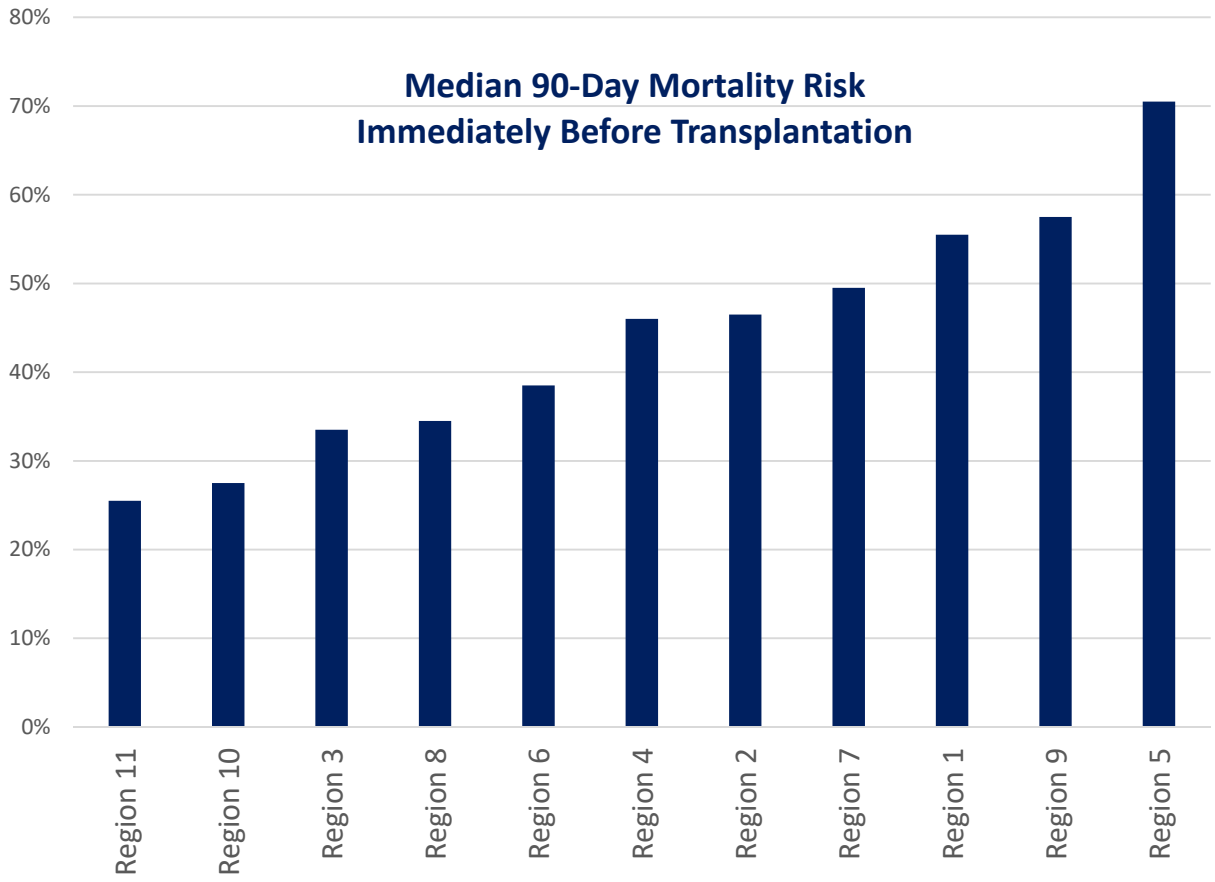


[2] Source: SRTR website for each transplant center.

90. Median MELD at Transplant. The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee identified variance in median MELD at transplant as "a disparity metric for liver distribution." Exhibit G at p. 9. MELD score is a measure of short-term (3 month) mortality or the likelihood that a candidate will die within three months without a transplant. The higher the MELD score the more likely the candidate will die. Thus variance in median MELD at transplant measures the difference in the likelihood of near term death of a candidate if they are not transplanted.

91. The variation in median MELD across the United States shows that where you live makes a big difference not only on how long you may need to wait for a transplant but also the likelihood of you dying or becoming too sick for transplant before a suitable donor liver become available.

92. The table below, which is based on 2017 SRTR data, shows the difference in mortality risk for a patient at the median MELD at transplant for each UNOS Region if they did not receive a transplant within 90 days. A patient in Region 5, which includes California, is likely to be transplanted when they have an over 70% chance of dying within 90 days without a transplant, as compared to a patient in Region 10 or Region 11 which has a 25% to 28% chance of dying within 90 days without a transplant. The three Regions with the highest median MELD score include California, Massachusetts and New York.



93. As told by Dr. Ryutaro Hirose, former chair of the OPTN/UNOS Liver & Intestinal Organ Committee, "[i]t turns out that because of the way the lines are drawn, in some areas of the country you have to achieve a much higher MELD score to get a transplant than you do in other parts of the country."[3]

I. Domestic Transplant Tourism

94. Given the disparity in wait times and waitlist mortality between different areas of the United States, liver candidates with financial resources often relocate to be listed at transplant centers in areas with shorter wait times. In 2013, approximately one in five liver transplants

[3] https://arstechnica.com/science/2017/03/live-death-math-and-efficiency-the-quest-to-solve-us-organ-transplants-woes/

were performed on candidates who traveled out of state for a transplant. Exhibit N - Financial Considerations: Costs to Patients at p. 10.

95. Transplant centers in low wait-time areas take advantage of the geographic disparity in liver allocation and advertise their low wait times. For example, Methodist University Hospital in Memphis advertises that "patients that are on our list have a shorter waiting time."[4] Ochsner Health System in New Orleans advertises that "[t]he most recent median wait time for a liver transplant surgery at Ochsner is two months compared to 16 months nationwide"[5] and touts its shorter wait times on its website.[6]

96. Not surprisingly, liver candidates with financial resources take advantage of the disparity in wait times and fly cross-country to receive liver transplants. In 2009, Steve Jobs (then-CEO of Apple) famously flew cross-country to Methodist University in his Learjet to receive a liver transplant because "patients in Northern California wait more than six years, on average, for a liver transplant, whereas the majority of patients in Tennessee receive new livers in less than three months." See generally, Peter Ubel, Your New Liver Is Only A Learjet Away: Parts 1-3.[7]

97. Mr. Jobs broke no laws by listing as a candidate in multiple locations, and in fact UNOS rules actually *require* doctors to discuss with candidates the option of multi-listing. Multi-listing is not a financially viable option for candidates who do not have portable insurance

[4] http://www.methodisthealth.org/healthcare-services/transplant/organ-transplants-in-tennessee/liver-transplants/ at 1:00.

[5] https://www.ochsner.org/services/liver-transplants

[6] https://www.ochsner.org/services/liver-transplants/liver-transplant-statistics/

[7] https://www.forbes.com/sites/peterubel/2015/06/24/your-new-liver-is-only-a-learjet-away-first-of-three-parts/#5fda0e3d2e56

coverage and who lack the means to travel to other transplant centers which may be hundreds of miles away.

98. The cost of traveling for a liver transplant is significant. As an initial matter, Plaintiffs, like many liver candidates, would not have insurance or Medicaid coverage if they travelled for a liver transplant and do not have the hundreds of thousands of dollars necessary to privately pay for a transplant. Moreover, apart from the costs of the actual transplant, unless one has access to a private jet, they must travel and wait away from home for a liver for an indeterminate amount of time. These travel and lodging costs for a patient and caregiver for an extended period of time can be prohibitively expensive for many. Exhibit N - Financial Considerations: Costs to Patients.

99. As summarized by Dr. Dorry Segev of John Hopkins, the disparity in liver distribution "builds a system by which those who are rich and powerful can get organs from anywhere in the country" and "[t]hose who don't have the resources to travel, don't have access to a private jet, don't have the resources to even get evaluated by other transplant centers, and are stuck with the care around where they live, they get disenfranchised by the system." [8]

J. HHS, OPTN and UNOS Have Failed to Bring Liver Policy Into Compliance with the Final Rule

100. OPTN and UNOS have been trying to develop an equitable liver allocation policy for over 30 years. Over this time period, there have been countless proposals, recommendations, studies, advisory committees, ad hoc committees, liver subcommittees, working groups, public forums and policy initiatives. Despite all this effort, there has been only incremental improvement in the liver allocation policy. The policy remains fundamentally

[8] https://arstechnica.com/science/2017/03/live-death-math-and-efficiency-the-quest-to-solve-us-organ-transplants-woes/

flawed and unlawful because it distributes livers on a "local first" basis, in contravention of Congress' mandate and the Final Rule.

(a) Opposition to Lawful and Equitable Liver Distribution

101. The institutional paralysis at OPTN and UNOS is due, in part, to a vocal group that opposes equitable liver distribution and has resisted meaningful change in OPTN Policy for the last few decades. They oppose equitable liver allocation for two reasons: they believe in "local first" organ distribution and they benefit operationally and financially from the illegal and inequitable status quo of the current system.

102. Local First. There are those who disagree with the premise of NOTA and the idea of geographic equality in organ distribution. They continue to believe that organs should remain local and have continuously pushed a "local first" agenda with OPTN and UNOS. See e.g., October 13, 2016 letter from Representative Lynn A. Westmoreland of Georgia to HRSA expressing concerns an OPTN/UNOS proposal "would have a negative impact on liver transplant candidates in Georgia and the Southeastern region overall. Specifically, the proposed redistricting would reduce the number of liver transplants performed in Georgia by a minimum of 20%." See also June 29, 2018 letter from Piedmont Hospital to HHS at p. 2 (opposing any change to liver allocation policy because it "will ship livers away from communities in Georgia to New York, resulting in irreparable harm to Georgians on the transplant list.")

103. This school of thought appears to be rooted in the mistaken belief that organ donors would be more willing to donate organs if the organs would be used locally. There is no basis to this claim. HHS sponsored studies have shown that the vast majority of organ donors would like their "organs to go to the more medically urgent patients regardless of where they live in the U.S." and there is no link between organ donation and distribution policies. Exhibit

O – 2012 National Survey of Organ Donation Attitudes and Behaviors at Table 28. Moreover, the states that provide the most organs to the system are among those with the longest liver wait times. For example, Californians donate more organs that any other state, yet California has the longest liver wait time and highest median MELD at transplantation. There is no legal, medical or factual link between local organ allocation and increased organ donation.

104. The Business of Liver Transplant. Liver transplant is a multi-million dollar business. A 2017 Milliman report estimates that the average liver transplant results in total billed charges of $812,500. Transplant centers in short wait list areas can do 100 to 200 transplants per year, including many for out-of-state residents who fly to these transplant centers because of their shorter waiting times. Some of the largest of these centers perform a significant percentage of their liver transplants in people from outside their local area. As noted in the New England Journal of Medicine, "broader organ sharing is opposed by some smaller transplant programs, in part because they want to be able to offer a full range of services to patients in their care and in part because they would stand to lose business under such a system." See also New England Journal of Medicine 371:26 at 2449 ("Timothy Schmitt, who directs the University of Kansas Hospital Center for Transplantation, says he finds the model 'nearsighted' and that his center would stand to lose 30 to 40% of its transplantation practice if these changes are implemented.")

105. Notably, the resistance to equitable liver allocation is most vocal and pronounced by those who benefit most from the current system, i.e., those transplant centers that have short liver transplant wait times and therefore serve as destinations for those who are wealthy enough to travel for a liver transplant. An analysis of the public comments made by transplant professionals on the UNOS/OPTN website against equitable liver allocation (as of November

2016) shows that a vast majority of those opposing the new proposal came from Texas, Georgia, Missouri, North Carolina, Kentucky, Kansas and Louisiana, states that have low median MELD scores and short wait times.[9] Support for "local" transplant policies in these parts of the country is pretextual. At the heart of support for status quo allocation policies is the financial advantage enjoyed by transplant centers with short wait times that perform a substantial number of transplants on candidates from outside their local areas.

106. Regardless of the motivations of those that oppose revisions to the OPTN liver distribution policy, Congress made clear, years ago, that organs are a national resource and neither financial gain nor the protections of one's own patients or transplant program is an appropriate or legally supportable basis for organ distribution.

(b) Process, Process and More Process

107. Judicial intervention is necessary because HHS, OPTN and UNOS have shown themselves incapable of implementing a lawful and equitable liver distribution policy. OPTN and UNOS have had decades of process, meetings and reports but have been unable to implement the necessary change.

108. OPTN's website contains a timeline showing "major milestones in liver allocation and distribution policy development." https://optn.transplant.hrsa.gov/governance/policy-initiatives/liver-timeline/.

- 1987 to 2002 (**fifteen years**). The first liver policy was developed in 1987 but it was not until 2002 that OPTN implemented the MELD/PELD score system to provide an "objective measure of medical urgency."

[9] https://keeptransplantsfair.org/wp-content/uploads/2017/05/Liver-Allocation-Public-Comments-2016.pdf

- 1990 to 2005 (**fifteen years**). In 1990, Congress revised NOTA to make clear that organs should be distributed on a nationwide basis but it took OPTN until 2005 to transition from a purely local system, giving first priority to the DSA, to a system that provided "Regional sharing for candidates with MELD scores of 15 or greater." During this same time period, over 25,000 people on the liver wait list died or became too sick to be transplanted.
- 2010 (**additional five years**) – OPTN moves to "Regional Sharing for Status 1 candidates." During these five years, over 12,000 people on the liver wait list died or became too sick to be transplanted.
- 2012 to 2018 (**six years**). In 2012, HHS Advisory Committee recommends "that organ allocation should be evidence-based and not based on the arbitrary boundaries of OPOs or their DSAs," but nothing has really changed in the last six years. OPTN "adopted a strategic plan" (2012), established "organ-specific committees" (2012), released a "concept paper" (2014), held a "public forum" (2014), held a "2nd Public Forum" (2015), had a "public comment proposal" (2016), had a "second public comments proposal" (2017). The final proposal, adopted by the OPTN Board but not implemented, remains – contrary to HHS Advisory – "based on the arbitrary boundaries of OPOs or their DSAs." During this six year period, over 17,000 people on the liver wait list died or became too sick to be transplanted and additional people die every day.

109. On December 1, 2017, Tamiany de La Rosa, a 25-year-old New York woman on liver transplant list requested the Acting Secretary of HHS "set aside those portions of OPTN Policy 9 that require livers from deceased donors to be allocated to candidates based on

arbitrary geographical boundaries instead of medical priority." December 1, 2017 letter from M. Shulman to Acting Secretary of HHS attached as Exhibit P.

110. Three months later, HHS responded by acknowledging that "geographic disparities in liver allocation were unacceptably high," recognizing that OPTN had "discussion" and "proposals" for six years and promised to "monitor developments regarding proposed changes to OPTN's liver allocation policy to ensure compliance with the National Organ Transplant Act of 1984, as amended, and the OPTN Final Rule." March 1, 2018 letter from G. Sigounas at HHS to M. Shulman attached as Exhibit Q.

111. On May 30, 2018, Plaintiffs requested that the Secretary take action and exercise his obligation and authority to ensure OPTN policy complies with NOTA and the Final Rule. Plaintiffs specifically requested that the Secretary direct "the OPTN to set aside those portions of OPTN Policy 9 that require livers from deceased donors to be allocated to candidates based on arbitrary geographic boundaries instead of medical priority" and "direct the OPTN to immediately revise the distribution of livers to follow a zone based distribution consistent with both the law and how other organs (*e.g.*, lungs and hearts) are distributed." May 30, 2018 letter from M. Shulman to Secretary of HHS attached as Exhibit R.

112. On June 8, 2018, HHS responded that it "requested that the OPTN provide its views on the issues raised in your letter," including whether the OPTN liver policy is consistent with the requirements of NOTA and the Final Rule. June 8, 2018 letter from G. Sigounas at HHS to M. Shulman attached as Exhibit S. In its request to OPTN, HHS specifically requested OPTN's views on whether the following four aspects of OPTN liver allocation policy is consistent with NOTA and the Final Rule: "(1) using DSAs as units of allocation; (2) using OPTN regions as units of allocation, alone or in combination with a nautical circle originating from donor hospitals; (3) using proximity points in relation to DSAs; and (4) using medial

MELD in DSAs in granting exception points to transplant candidates." June 8, 2018 letter from G. Sigounas at HHS to Yoland Becker, MD at OPTN attached as Exhibit T.

113. On June 12, 2018, the OPTN Board of Directors accepted the Recommendations Report of the OPTN/UNOS Ad Hoc Committee on Geography ("Ad Hoc Committee") and passed a resolution reiterating that "[d]eceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied." In its report, the Ad Hoc Committee "identified three frameworks for geographic distribution that it finds to be consistent with" NOTA and the Final Rule: (i) zone-based distribution using a fixed distance from the donor hospital (the current system for lung distribution); (ii) mathematically optimized distribution using objective metrics instead of "arbitrarily defined geographic borders"; and (iii) "organ distribution without geographic boundaries." Exhibit U – OPTN/UNOS Ad Hoc Committee on Geography, Geographic Organ Distribution Principles and Models Recommendations Report at p. 5. The current system of DSA or Regional-based distribution was not approved as a distribution method that is consistent with NOTA and the Final Rule.

114. Despite a clear record that the current liver policy is illegal and inequitable, at the June 12, 2018 Board Meeting, the OPTN Board of Directors did not recommend any changes to the liver distribution policy. Instead it suggested additional "community feedback," more "policy analysis" and additional committee meetings. Id. at p. 10.

115. On June 25, 2018, OPTN responded to HRSA letter of June 8, 2018. In classic OPTN doublespeak, the OPTN made clear that use of DSAs and Regions are improper and inconsistent with the Final Rule – "the OPTN previously recognized and again confirms that DSAs are not a good proxy for geographic distance between donors and transplant candidates

because the disparate sizes, shapes, and populations of DSAs as drawn today are not rationally determined in a manner that can be consistently applied equally for all candidates." Exhibit E at p. 2. Similarly, the OPTN found that "like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates." Id. at p. 3.

116. Unfortunately, instead of taking action to abolish an illegal and inequitable policy, the OPTN took the position that, after decades of apparently futile deliberation, yet more review, discussion and public comment was necessary and took no meaningful action.

117. As of the filing of this suit, the Secretary has refused to take any action to bring the OPTN liver allocation policy into compliance with the law.

118. It is HHS, OPTN and UNOS' responsibility to implement Congress' policy mandate. They have failed to do so for the last three decades and absent judicial intervention may not act for another three decades.

CLAIMS FOR RELIEF

COUNT I – ADMINISTRATIVE PROCEDURES ACT, 5 U.S.C. § 706(2)(A)-(D) THE SECRETARY'S ACTIONS ARE NOT IN ACCORDANCE WITH LAW

119. Plaintiff repeats and incorporates by reference the allegations contained in prior paragraphs.

120. Under the APA, a court reviewing a final agency action must "hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and (D) without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

121. The OPTN liver allocation policy is not in accordance with law because it arbitrarily deprives candidates with the greatest medical need for liver transplants of the opportunity to receive such transplants.

122. The OPTN liver allocation policy is not in accordance with law because it fails to promote the nationwide distribution of organs *equitably* among transplant patients, as required by NOTA. 42 U.S.C. § 274(b)(2)(D).

123. The OPTN liver allocation policy is not in accordance with law because the policy does not result in the equitable allocation of cadaveric organs, as required by 42 C.F.R. § 121.4(a)(l).

124. The OPTN liver allocation policy is not in accordance with law because the policy does not result in the equitable allocation of cadaveric organs, as required by 42 C.F.R. § 121.4(a)(l).

125. The OPTN liver allocation policy is not in accordance with law because the policy does not allocate livers "based on sound medical judgment," as required by 42 C.F.R. § 121.8(a)(l).

126. The OPTN liver allocation policy is not in accordance with law because the policy does not allocate livers in a manner that seeks to "achieve the best use of donated organs," as required by 42 C.F.R. § 121.8(a)(2).

127. The OPTN liver allocation policy is not in accordance with law because the policy allocates livers "based on the candidate's place of residence or place of listing," in a manner that directly violates 42 C.F.R. § 121.8(a)(8).

128. The OPTN liver allocation policy is not in accordance with law because it fails to achieve and in fact directly undermines the "performance goal" of "[d]istributing organs over as

broad a geographic area as feasible . . . and in order of decreasing medical urgency," as required by 42 C.F.R. § 121.8(b)(3).

COUNT II – ADMINISTRATIVE PROCEDURES ACT, 5 U.S.C. § 706(2)(A)
THE SECRETARY'S ACTIONS ARE
ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION

129. Plaintiffs repeat and incorporate by reference the allegations contained in prior paragraphs.

130. The Secretary's action not to set aside the OPTN liver allocation policy was arbitrary, capricious, and an abuse of discretion because the Secretary had no sound reason for leaving in place a policy that is illegal and inequitable, and serves no valid purpose.

COUNT III – VIOLATION OF THE DUE PROCESS CLAUSE

131. Plaintiffs repeat and incorporate by reference the allegations contained in prior paragraphs.

132. The Due Process Clause of the United States Constitution provides that "[n]o person shall be … deprived of life, liberty, or property, without due process of law …"

133. HHS is a federal agency. HHS has delegated liver distribution to UNOS and OPTN. The OPTN liver policy constitutes state action. HHS's refusal to change the liver allocation policy similarly constitutes state action.

134. The Due Process Clause requires the federal government to treat similarly situated people equally. Whenever the federal government classifies people to ration a benefit or other resource, such as deceased donor organs, the classification is subject to scrutiny.

135. Donated livers are a resource necessary to sustain the lives of potential recipients. Deprivation of a life-sustaining right constitutes the government's deprivation of a fundamental

right to those candidates. Classifications that result in distribution of resources necessary for life are subject to heightened scrutiny from the judicial system.

136. The current policy allocating donated livers – and the Secretary's refusal to change it -- fail to pass review under heightened scrutiny. The policy does not further an important government interest. Rather, the current policy protects the financial position afforded to transplant programs in areas with short waitlists.

137. Even if heightened scrutiny does not apply, the current deceased donor liver allocation policy – and the Secretary's refusal to change it – are not in accordance with the law because those actions are arbitrary, capricious, and not rational. The actions thus fail rational basis review, as the interests behind the current policy are not related to any legitimate government interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court:

A. declare that OPTN liver distribution policy based on arbitrary DSA or Region areas violates NOTA (and regulations promulgated thereunder), which requires a "nationwide distribution of organs equitably among transplant patients."

B. require the Secretary and OPTN to implement an appropriate zone-based liver distribution policy (e.g., 1,000 miles) within 6 months;

C. enjoin the Secretary and OPTN from implementing a new liver allocation policy that is inconsistent with the requirement that livers be equitably allocated among transplant patients; and

D. such other relief as is just and proper.

Dated: Armonk, New York
July 13, 2018

By: _____

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